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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,584	10/31/2003	Phillip B. Messersmith	7317	1890
22922	7590	03/14/2006	EXAMINER	
REINHART BOERNER VAN DEUREN S.C. ATTN: LINDA KASULKE, DOCKET COORDINATOR 1000 NORTH WATER STREET SUITE 2100 MILWAUKEE, WI 53202			KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,584

Applicant(s)

MESSERSMITH ET AL.

Examiner

Rosanne Kosson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 28, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a composition comprising a polymer conjugated to an acyl donor peptide, a polymer conjugated to an acyl acceptor peptide, and transglutaminase, classified in class 435, subclass 193.
- II. Claims 14-20, drawn to a method of using a biomimetic peptide for gelation, classified in class 435, subclass 193.
- III. Claims 21-32, drawn to a cross-linked hydrogel comprising the enzymatic transfer product of AC-PEG-AC linked to $H_{4-n}C-(PEG-AD)_n$, classified in class 523, subclass 511.
- IV. Claims 33-39, drawn to a cross-linked hydrogel comprising alginic acid conjugated to an acyl acceptor peptide which is linked to PEG conjugated to an acyl donor peptide, classified in class 435, subclass 101.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IV are related in that each comprises a polymer, an acyl donor peptide and an acyl acceptor peptide. But, inventions are separate and distinct if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group I has three separate components, including an enzyme that is not present in the inventions of Groups III and IV. Also, the polymer or polymers of Group I

need not be alginic acid or PEG- they be proteins for example. As a result, Group I is chemically, structurally and functionally distinct from Groups III and IV.

The inventions of Groups III and IV each comprise PEG, an acyl donor peptide and an acyl acceptor peptide. But, Group III comprises PEG conjugated to the acyl acceptor peptide, while Group IV comprises alginic acid conjugated to the acyl acceptor peptide. Also, in Group IV, the PEG may be conjugated to the acyl donor peptide in any fashion, while the conjugation in Group III has a specific structure ($H_{4-n}C-(PEG-AD)_n$). Because these compositions are chemically and structurally different, the inventions are patentably distinct.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of Group I may be used in a different method. The composition of Group I comprises a polymer conjugated to an acyl donor peptide, a polymer conjugated to an acyl acceptor peptide, and transglutaminase. The two polymers may be two different proteins, such as therapeutic compounds that may be linked to each other by the reaction of transglutaminase with the donor and acceptor peptides to form pharmaceuticals. The proteins may be, e.g., diphtherotoxin and IL-6 or a carcinostatic protein and a monoclonal antibody, two combinations which are used as anti-cancer drugs (see Takahara et al., US 6,010,871, col. 1, lines 57-65). Also, one polymer may be a gene and the other polymer may be an orosomucoid protein, a combination that forms a gene therapy drug (see Takahara et al., col. 1, line 58, to col. 2, line 10). Thus, the preamble of a

biomimetic gelation system is an intended use of the composition of Group I, but it is not the only use. Therefore, these inventions are patentably distinct.

The inventions of Groups II and III are related in that the method of Group II uses a polymer conjugated to an acyl acceptor peptide and a polymer conjugated to an acyl donor peptide, which are elements of the composition of Group III. But, the polymers in Group II need not be PEG, are not linked to each other, and the composition of Group III is not required for the method of Group II. Therefore, these inventions are patentably distinct.

The inventions of Groups II and IV are related in that the method of Group II uses a polymer conjugated to an acyl acceptor peptide and a polymer conjugated to an acyl donor peptide, which are elements of the composition of Group III. But, the polymers in Group II need not be PEG or alginic acid, are not linked to each other, and the composition of Group IV is not required for the method of Group II. Therefore, these inventions are patentably distinct.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

Art Unit: 1653

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

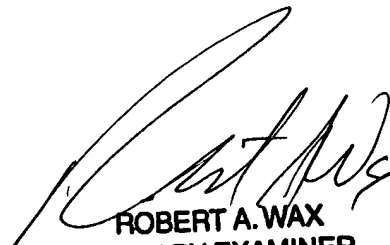
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-03-08



ROBERT A. WAX
PRIMARY EXAMINER